

## Pharmacy Medical Necessity Guidelines: Xadago® (safinamide)

Effective: April 14, 2020

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM
<p>These pharmacy medical necessity guidelines apply to the following:</p> <p><b>Commercial Products</b></p> <input type="checkbox"/> Tufts Health Plan Commercial products – large group plans <input type="checkbox"/> Tufts Health Plan Commercial products – small group and individual plans <input type="checkbox"/> Tufts Health Freedom Plan products – large group plans <input type="checkbox"/> Tufts Health Freedom Plan products – small group plans <ul style="list-style-type: none"> <li>CareLink<sup>SM</sup> – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization</li> </ul> <p><b>Tufts Health Public Plans Products</b></p> <input type="checkbox"/> Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product) <input checked="" type="checkbox"/> Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans <input type="checkbox"/> Tufts Health RITogether – A Rhode Island Medicaid Plan		<p><b>Fax Numbers:</b></p> <p>RXUM: 617.673.0988</p>	

**Note:** This guideline does not apply to Medicare Members (includes dual eligible Members).

### OVERVIEW

Xadago (safinamide) is a monoamine oxidase inhibitor type-B (MAOI-B) indicated for the adjunctive treatment of patients with Parkinson’s Disease (PD) who are experiencing “off” episodes. Xadago has not been shown to be effective as monotherapy for the treatment of PD.

An “off” episode is a time when a patient’s medications are not working well, causing an increase in Parkinson disease symptoms, such as tremor and difficulty walking.

### COVERAGE GUIDELINES

1. Diagnosis of Parkinson’s Disease and member is experiencing “off” time on levodopa/carbidopa monotherapy
- AND**
2. Xadago is prescribed in combination with levodopa/carbidopa
- AND**
3. Member tried and could not tolerate treatment due to adverse effects or there was inadequate response with ALL of the following preferred generic alternatives:
    - a. rasagiline
    - b. entacapone

### LIMITATIONS

None

### CODES

None

### REFERENCES

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12. National Institute for Health and Care Excellence. Parkinson's Disease; National Clinical Guidelines for Diagnosis and Management in Primary and Secondary Care. 2006.
13. Pahwa R., Factor S.A., Lyons K. E., et al. Practice Parameter: Treatment of Parkinson disease with motor fluctuations and dyskinesia (an evidence-based review). *Neurology*. April 2006; 66:983-995.
14. Parkinson Study Group. A Randomized Placebo-Controlled Trial of Rasagiline in Levodopa-Treatment Patients with Parkinson Disease and Motor Fluctuations: The PRESTO Study. *Arch Neurol*. 2005; 62(2):241-248.
15. PerezLioet S, Negre-Pages L, Damier P, et al. Prevalence, determinants, and effect of quality of life of freezing of gait in Parkinson disease. *JAMA Neurol*. 2014; 71, 884-890.
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17. Xadago prescribing information. Louisville, KY: Newron Pharmaceuticals, SpA; May 2017.

#### **APPROVAL HISTORY**

December 12, 2017: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. November 13, 2018: No changes.
2. November 12, 2019: Administrative update to add description of "off-episodes" to the overview section.
3. April 14, 2020: Effective April 14, 2020 Xadago MNG applies to MA and RITogether plans only. Xadago criteria has been added to Medications for the Management of Parkinson's Disease MNG (ID: 6546248) for Commercial and Direct Plans. No criteria changes.

#### **BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION**

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.